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10/550,073	08/20/2007	Pascale Adolphine Meuter	TC-CarCere-DPW091505-lyh-	2162
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EXAMINER ARNOLD, ERNST V				
ART UNIT		PAPER NUMBER		
1613				
NOTIFICATION DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

# Office Action Summary

**Application No.**

10/550,073

**Applicant(s)**

MEUTER ET AL.

**Examiner**

ERNST V. ARNOLD

**Art Unit**

1613

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-942)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/3/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

Claims 1-13 are pending and under examination.

**Comment:** Independent claims should begin with "A", for example: A method of... Claims dependent therefrom should begin with "The", for example: The method of claim 1...

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

The GB 2353933 reference only has the even pages provided to the Examiner. Therefore the reference is only being considered to the extent of the subject matter provided to the Examiner.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board

of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance:

1. Claim 1 recites the broad recitation greater than 0.25, and the claim also recites preferably greater than 0.30 and at least 0.40 which are the narrower statements of the range/limitation.
2. Claim 2 recites the broad recitation greater than 100, and the claim also recites preferably greater than 150, preferably greater than 200 and preferably greater than 250 which are the narrower statements of the range/limitation.
3. Claim 3 recites the broad recitation greater than 0.25, and the claim also recites preferably greater than 0.30 and at least 0.40 which are the narrower statements of the range/limitation.
4. Claim 7 recites the broad recitation greater than 0.25, and the claim also recites preferably greater than 0.30 and at least 0.40 which are the narrower statements of the range/limitation.

5. Claim 13 recites the broad recitation of at least 4, and the claim also recites preferably of at least 5 and more preferably more than 7 which are the narrower statements of the range/limitation.

Claims 4-6 and 8-12 are rejected as indefinite because they are dependent on an indefinite base claim.

**Claim Rejections - 35 U.S.C. §§ 101 and 112, Second Paragraph**

The following are quotations of 35 U.S.C. §§ 101 and 112, second paragraph, respectively, which form the basis of the claim rejections as set forth under this particular section of the Official Action:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **7-10** are rejected under 35 U.S.C. § 101 as being drawn to use claims, which are non-statutory process claims, as defined in 35 U.S.C. § 101. See, *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967). In addition, claims **7-10** are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, a claim is rendered indefinite when said claim merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2175.03(q). As a result, the Applicants are respectfully required to redraft the

aforementioned use claims as statutory process claims that delimit active, positive steps on how to use a composition according to the invention as originally filed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Oobae et al. (US 2002/0042393).

Oobae et al. disclose crystalline trehalose having a purity of 99.0% or more, a proportion of particles of 75 microns or more of 2 to 90%, an average particles size of 10 to 250 microns, and an apparent specific volume of 1.5 to 3.5 ml/g (Abstract; [0037-0041]; and claims 1 and 11). Oobae et al. direct the artisan to trehalose dihydrate in the crystalline state [0025 and 0035]. Since specific volume is the reciprocal of density then the density of the trehalose particles is from 0.66 to 0.28 g/ml. The Examiner notes that the instant specification teaches that the particles have a density of 0.61 g/cm<sup>3</sup> which correlates to a specific volume of 1.6 cm<sup>3</sup>/g, which is within the specific volume range disclosed by Oobae et al. It is therefore the Examiner's position that since the size of the particles is the same, and hence the radius of the particles is the same, and the density is the same, which defines the mass per unit volume, then the instantly claimed specific surface area greater than 0.25 m<sup>2</sup>/g is inherent in the particles of Oobae et al.

Oobae et al. simply did not make this measurement. From MPEP 2131.02 III: "Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999)".

Therefore, the Examiner reasonably concludes that instant claims 1 and 2 are anticipated. Oobae et al. disclose tablets, hence for human ingestion, containing the trehalose that can also contain cosmetic powders ([0045-0048, 0061-0066, 0095-0096]; and claims 8 and 9). Thus, instant claims 11 and 12 are anticipated. It is the Examiner's position that, since the trehalose tablets of Oobae et al. has the same components then they will have the same tensile strength as instantly claimed in claim 13; Oobae et al. simply did not measure it. From MPEP 2112.01: I and II: "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." "A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)".

Accordingly, the Examiner reasonably concludes that Oobae et al. anticipate instant claims 1, 2 and 11-13.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oobae et al. (US 2002/0042393), as applied to claims 1, 2 and 11-13 above, in view of Kinouchi (US 5441644) and JP2001213890 (IDS filed 7/3/06).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was



not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant claims trehalose solids, compositions and process for preparing crystalline or semi-crystalline trehalose solids.

### **Determination of the scope and content of the prior art**

#### **(MPEP 2141.01)**

The reference of Oobae et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Kinouchi teaches "For crystallizing trehalose from an aqueous trehalose containing solution, the solution is first concentrated to provide a dissolved trehalose concentration of approximately 50 to 100, preferably 60 to 80, more preferably 70 to 75 g/dl while the temperature of the solution is adjusted to about 20 to 100, preferably 40.degree. to 80.degree. C., and, optionally, fine powdery crystals of trehalose dihydrate are seeded to the concentrated solution to induce the generation or growth of new crystals. After the seeded or spontaneous generation and/or growth of new crystals, the slurry can be further concentrated to provide a total trehalose concentration of approximately from 75 to 100, preferably 85 to 93 g/dl total trehalose, and this further concentrated solution is gradually cooled to a temperature of from 5.degree.

to 20.degree. C. to further grow the crystals. Then, the solution is allowed to stand for about 30 minutes to 2 hours to decrease or eliminate supersaturation, and it is then subjected to solid-liquid separation, and the crystals thus separated are washed with a small amount of water. In this way, highly-pure trehalose dihydrate crystals having a purity of 99% or more can be obtained." (column 4, lines 31-54). The Examiner interprets the "solid-liquid separation" to read on applying a shear. Also see column 6, lines 20-43 and Example 2 where centrifugation is used to separate the crystals, hence an applied shear, and dried at reduced pressure.

JP2001213890 teaches trehalose particles that can be used in pharmaceuticals, cosmetics, foods, bath agents, veterinary products, diagnostic products, agrochemicals and fertilizers (Abstract).

**Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

1. The difference between the instant application and Oobae et al. is that Oobae et al. do not expressly teach the instantly claimed method of making the trehalose. This deficiency in Oobae et al. is cured by the teachings of Kinouchi.

2. The difference between the instant application and Oobae et al. is that Oobae et al. do not expressly teach products for detergents, fertilizers or agrochemicals containing the crystalline or semi-crystalline trehalose solids. This deficiency in Oobae et al. is cured by the teachings of JP2001213890.

**Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make crystalline trehalose by heating an aqueous solution of trehalose above its temperature of solubility, applying shear and cooling to obtain trehalose solids, as suggested by Kinouchi, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Oobae et al. teach using trehalose of 99% purity or higher and Kinouchi teaches a method of obtaining trehalose of 99% purity or higher. It is the Examiner's position that at least 5% water based on dry substance of trehalose is intrinsic to the method of Kinouchi given the concentrations taught by Kinouchi above, in the absence of evidence to the contrary.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the composition of Oobae et al. for detergents, fertilizers or agrochemicals containing the crystalline or semi-crystalline trehalose solids, as suggested by JP2001213890, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because what one does with the composition is merely judicious selection of uses as taught by JP2001213890.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/  
Primary Examiner, Art Unit 1613